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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,818	01/09/2002	David R. Elmaleh	MGA-004.25	2433

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/25/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,818

Applicant(s)

ELMALEH ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 11, filed 6/9/03, wherein the specification and claims 1, 2, 9, and 12 were amended and claims 5 and 18 were amended.

Note: Claims 1-4 and 6-17 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to imaging agent, method of use thereof, and a kit wherein the agent comprises a radionuclide and a targeting moiety selected from the group consisting of cells, colony stimulating factors, platelet factor 4, growth factors, cytokines, interferon, tumor necrosis factors, cellular sources of energy for metabolic active plaque formation, lipids, lipid receptors, and components of clotting cascades.

Note: It should be noted the recitation that of the intended utility (i.e., the imaging agent will be used for cardiovascular use) in the preamble does not impart patentability to a known composition. Likewise, it should be noted that the preamble (i.e., 'cardiovascular') has not been given patentable weight because a preamble is denied the effect of a limitation wherein the portion of the claim following the preamble is a self-contained description not dependent upon the introductory clause for completeness.

Also, it should be noted that the specified targeting moieties all inherently comprise a component of a process involved in plaque formation as set forth in Applicant's claims.

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RESPONSE TO APPLICANT'S AMENDMENT

3. The Applicant's arguments filed 6/9/03 (Paper No. 11) to the rejection of claims 1-18 made by the Examiner under 35 USC 102, 103, and/or double patenting have been fully considered and deemed non-persuasive. Thus, all of the outstanding rejections are MAINTAINED for reasons of record in the office action mailed 2/5/03, Paper No. 9, and those set forth below.

Double Patenting Rejection

The rejection of claims 1-4 and 6-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6-9, 12-14, 16, 17, 31, 33, and 35 of US Patent No. 6,299,857 is MAINTAINED for reasons of record in the office action mailed 2/5/03, Paper No. 9.

Note: It is duly noted that Applicant has requested that the obviousness-type double patenting rejection be held in abeyance until claims are allowable.

102 Rejection

The rejection of claims 1-4 and 6-11 under 35 USC 102(e) as being anticipated by Edwards et al (US Patent No. 5,744,120) is MAINTAINED for reasons of record in the office action mailed 2/5/03 and those set forth below.

Applicant asserts that the claims have been amended to set forth specific targeting moieties. Also, Applicant asserts that to anticipate a claim, a single source must contain all the elements of the claim. Thus, since Edwards et al only disclose radiopharmaceuticals wherein the target moiety is cyclo(D-Val-Nme-Arg-Gly-Asp-

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Mamb), while other targeting moieties are taught, they are not enabled by Edwards and are excluded by the claims as amended.

It should be noted that Edwards et al disclose various possible biological molecules which may be conjugated to their radiopharmaceuticals. For example, in column 22, lines 53-54, it is disclosed that Q (biologically active molecule) may be platelet factor 4 or growth factors (PDGF, EGF, FGF, TNF, MCSF, or I11-8). Thus, since a Markush grouping of only two biologically active molecules (platelet factor 4 or growth factors, both of which are specifically listed as targeting agents) is disclosed, the skilled artisan would envision each member of the group being selected as Q given the limited number of possibilities of the Markush group. Furthermore, it should be noted that Edwards et al discloses that other biologically active molecules encompassed by the instant invention that may be used and specific documents wherein additional information may be found about the molecules. Note that some Q are directed to a single document (column 22, lines 9-55). Hence, the artisan having only a single choice would incorporate that Q into their imaging agent.

103 Rejection

The rejection of claims 12-17 as being rejected under 35 USC 103(a) as being unpatentable over Edwards et al (US Patent No. 5,744,120) is MAINTAINED for reasons of record in the office action mailed 2/5/03 and those set forth below.

Applicant asserts that the claims have been amended to set forth specific targeting moieties.

It should be noted that a reference is not limited to its preferred embodiments, but for what it discloses as a whole. Thus, Edwards et al discloses that Q may be platelet factor 4, growth factors, (i.e., PDGF), colony stimulating factors (MCSF), tumor necrosis factors (TNF), fibrinogen (component of clotting cascade), thrombin (component of clotting cascade), and leukocyte binding peptides (these would bind to cells (leukocytes)), all of which are encompassed by the instant invention [see column 5, lines 30-31; column 22, lines 17-18, 22-24, 28-29, 31, 41-42, and 53-55].


4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
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August 14, 2003